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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,731	02/04/2002	Jeffrey Morse Holloway	71086	8128

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EXAMINER

CHORBAJI, MONZER R

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 02/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/067,731	<b>Applicant(s)</b> HOLLOWAY ET AL.	
	<b>Examiner</b> MONZER R CHORBAJI	<b>Art Unit</b> 1744	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-8,10-15,19,20,22-37 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8,10-15,19,20,22-37 and 40-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

**This non-final action is in response to the RCE/Amendment received on 02/03/2005**

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 1-3, 5-8, 10-13, and 22-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163).

With respect to claims 1, 5, 8, 22, 26, and 29, the O'Dwyer reference teaches a method for inactivating microbes (col.3, lines 33-37) in a blood derived compounds (col.4, lines 5-6) including the following: illuminating with broad spectrum pulsed light (col.3, lines 32-38), a pulse or a flash (specification on page 5, numbered line 8 teaches the word pulses and the O'Dwyer reference uses both pulses or flashes in col.8, lines 35-35) duration of less than 100 ms (abstract, lines 12-13), wavelength range of 170 to 2600 nm (abstract, lines 14-15), exemplary fluence energy ranges (col.4, lines 41-44 or col.6, lines 41-44) that recites applying fluence energy at  $0.25 \text{ j/cm}^2$  or at  $0.05 \text{ j/cm}^2$  (col.6, lines 42-43), flowing blood derived compounds through a treatment chamber and illuminating while the compounds are flowing (col.7, lines 24-37), and a transmissive chamber to at least 1% of a light treatment (col.7, lines 26-32, col.9, lines 66-67, and col.10, lines 1-5 such that it is intrinsic that the treatment chamber must be transmissive to at least 1% of light in order to inactivate microbes in blood derived compounds). In addition, both the instant claims and the O'Dwyer reference discloses overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the value ranges for the fluence per flash recited in claims 1, 5, 8, 22, 26 and 29 is also an intrinsic value ranges for the O'Dwyer reference. Furthermore, with respect to claims 22, 26 and 29, the O'Dwyer reference does not add genotoxic

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chemical agents as defined in the specification on page 3, numbered lines 14-27.

Such chemicals require photoactivation to initiate the chemicals irreversible binding to nucleic acids. The O'Dwyer reference adds albumin (bovine serum) that functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. However, with respect to claims 1, 5, 8, 22, 26, and 29, the O'Dwyer reference fails to teach the following: illuminating a platelet composition, decreasing platelet aggregation by not more than about 40% and inactivating microbes in the platelet composition by at least about 2 logs. With respect to claims 1, 5, 8, 22, 26, and 29, the Horowitz reference teaches the following: a method of irradiating microbes in a platelet composition (col.6, lines 27-33) at least about 2 logs (col.10, lines 9-11). Further the Horowitz teaches that the platelet aggregation improved from about 70% to more than 90% of control levels, meaning that the decrease of platelet aggregation is not more than about 40%. Thus. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of O'Dwyer reference to include a step of pulsing platelet composition as taught by the Horowitz reference in order to inactivate viruses in platelet concentrates (col.3, lines 50-55).

With respect to claims 2, 6, 10-12, 23, 25, 27 and 30-33, the O'Dwyer reference teaches the following: illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15), a

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fluence of about 0.1 to about 0.6 j / cm<sup>2</sup> (abstract, lines 12-13), blood derived compounds is flowed through the treatment chamber at a constant flow rate (col.7, lines 24-32 such that in order to inactivate microbes it is intrinsic that the method of O'Dwyer reference is flowing blood compounds at a constant flow rate), both the instant claims and the O'Dwyer reference disclose overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the recited value range for the fluence per flash is also an intrinsic value range for the O'Dwyer reference, it is known for UV light to be concentrated at wavelengths within a range of 200 to 300 nm (col.2, lines 13-17) and a pulse duration of less than 100 ms (abstract, lines 13-14).

With respect to claim 3, 7, 13, 24, 28 and 34, the Horowitz reference teaches illuminating any type of platelet concentrates (col.3, lines 51-52,col.6, lines 29-30).

5. Claims 14-15, 19-20, 35-37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Dwyer et al (U.S.P.N. 6,312,931) in view of Horowitz et al (U.S.P.N. 5,981,163) and further in view of Platz et al (U.S.P.N. 6,187,572).

With respect to claims 14, 19, 35, and 40, the O'Dwyer reference fails to teach repeating the illumination of the platelet composition every 6 hours and not decreasing platelet aggregation by more than about 40%. However, with respect to claim 35, the O'Dwyer reference increases the shelf life of blood components by illuminating them with broad spectrum pulsed light. In addition, both the instant claims and the O'Dwyer reference discloses overlapping intensity or

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fluence range values and both use xenon flash lamps with the same wavelength range such that the value range for the fluence per flash recited in claims 19, 35 and 40 is also an intrinsic value range for the O'Dwyer reference. Furthermore, with respect to claims 35 and 40, the O'Dwyer reference does not add genotoxic chemical agents as defined in the specification on page 3, numbered lines 14-27. Such chemicals require photoactivation to initiate the chemicals irreversible binding to nucleic acids. The O'Dwyer reference adds albumin (bovine serum) that functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. The Horowitz reference teaches that the platelet aggregation improved from about 70% to more than 90% of control levels, meaning that the decrease of platelet aggregation is not more than about 40% but fails to teach repeating the illumination of the platelet composition every 6 hours. However, the Platz reference teaches repeating the illumination every 2 minutes for a total time of 10 minutes (col.28, lines 65-67 and col.29, lines 1-3) and also illuminating continuously for 6 hours (col.35, lines 37-38). In addition, the Platz reference teaches illuminating for 90 minutes to achieve a certain log viral reduction (col.35, lines 57-58). Thus. It would have been obvious to one having ordinary skill in the art to modify the method of the O'Dwyer reference to include a step of repeating illumination every certain number of hours as taught by the

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Platz reference in order to achieve a desired value for the log reduction of viruses (col.35, lines 57-58).

With respect to claims 15, 20, 36-37, and 41-42, the O'Dwyer reference teaches illuminating with pulses of light having wavelengths between 240 nm and about 280 nm (abstract, lines 14-15). In addition, both the instant claims and the O'Dwyer reference disclose overlapping intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the recited value range for the fluence per flash is also an intrinsic value range for the O'Dwyer reference.

### ***Response to Arguments***

6. Applicant's arguments filed 02/03/2005 have been fully considered but they are not persuasive.

On page 14 of the Remarks section, applicant argues that, "The range of 0.1 to about 0.25 J/cm<sup>2</sup> was determined by the inventors in the instant application to be useful for inactivating microbes in a biological composition. Advantageously, the lower fluence range was one of the reasons that the BSPL treatment worked without the addition of stabilizers or other chemicals as taught by the O'Dwyer et al. who adds albumin and Horowitz et al. who adds quenching agents." The examiner disagrees. The O'Dwyer reference, which uses BSPL (col.3, lines 32-38) to inactivate microorganisms provides various exemplary fluence energy ranges (col.4, lines 41-44 or col.6, lines 41-44) that recites applying fluence energy at 0.25 j/cm<sup>2</sup> or at 0.05 j/cm<sup>2</sup> (col.6, lines 42-43). The O'Dwyer reference further recites applying BSPL at 0.1 J/cm<sup>2</sup> (col.8, lines 54-



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57) depending on the desired degree of inactivation (col.8, lines 58-62). The O'Dwyer reference adds albumin (bovine serum) that functions only for protecting the biological integrity of biomolecules of interest (col.5, lines 1-5, 23-25 and lines 61-67 and col.6, lines 1-11) and does not simulate any binding to nucleic acids. The specification on page 15, example 4 teaches adding fetal bovine serum to aggregations of platelets and diluting the platelets in PAS II solution. Moreover, both the instant claims and the O'Dwyer reference discloses same intensity or fluence range values and both use xenon flash lamps with the same wavelength range such that the value range for the fluence per flash recited in the instant claims is also an intrinsic value range for the O'Dwyer reference. The Horowitz reference was combined to show that irradiating microbes in a platelet composition (col.6, lines 27-33) at least about 2 logs (col.10, lines 9-11) and improving the platelet aggregation is known and not for whether chemicals have been added to the composition or not. The instant claims do not exclude the addition of chemicals.

With regard to using the fluence value of the Horowitz reference, the examiner has withdrawn this recitation since the instant claims use BSPL treatment method.

On page 16 of the Remarks section, applicant argues that, "the methodologies described in the O'Dwyer and Horowitz utilize significantly different technologies for the sterilization of a biological composition and, in fact, teach away from each other." The examiner disagrees. The Horowitz reference was combined only to show that irradiating microbes in a platelet composition

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(col.6, lines 27-33) is conventional; that to decrease the amount of microbes by at least about 2 logs (col.10, lines 9-11) and improving the platelet aggregation (col.9, lines 60-63) is known and not for the method of treating microorganisms in biological fluids. The O'Dwyer reference teaches irradiating blood with BSPL with same wavelength, fluence and time values. As a result, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of O'Dwyer reference to include a step of pulsing platelet composition as taught by the Horowitz reference in order to inactivate viruses in platelet concentrates (col.3, lines 50-55).

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (571) 272-1271. The examiner can normally be reached on M-F 6:30-3:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (571) 272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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